**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 10, 2014

Spinal Elements, Incorporated
Julie Lamothe, Ph.D.
Regulatory Affairs and Quality Assurance Director
3115 Melrose Drive, Suite 200
Carlsbad, California 92010

Re: K133218
Trade/Device Name: Crystal®; Mosaic®; Vertu®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, OVE
Dated: November 7, 2014
Received: November 10, 2014

Dear Dr. Lamothe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K133218

Device Name
Crystal®; Mosaic®; Vertu®

Indications for Use *(Describe)*

Crystal®:
The Crystal® device is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

The Crystal® device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine (i.e., anterior plate systems).

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

Mosaic®:
The Mosaic® device is an interbody fusion device intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two, three, or four screws. The maximum number of screws should be used to ensure adequate fixation of the implant.

Vertu®:
The Vertu® device is a stand-alone interbody fusion device intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary
# Crystal®, Mosaic®, and Vertu®

## 510(k) Number K133218

## I. SUBMITTER

Spinal Elements, Inc.
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**Date Prepared:** December 4, 2014

## II. DEVICE

| | |
|---|---|
| **Proprietary Name** | Crystal®; Mosaic®; Vertu® Systems |
| **Common Name** | Intervertebral Body Fusion Device |
| **Device Classification** | 21 CFR 888.3080 (Appliance, Fixation Spinal Intervertebral Body) |
| **Proposed Regulatory Class** | Class II |
| **Device Product Code** | ODP – Crystal<br>OVE – Mosaic and Vertu |

## III. PREDICATE DEVICE

| | |
|---|---|
| **Primary Predicate Name** | Calix PC |
| **Regulatory Class** | Class II |
| **Submission No** | K112036 |
| **Device Code** | ODP |
| | |
| **Predicate Name** | Crystal®; Mosaic®; Vertu® Systems |
| **Regulatory Class** | Class II |
| **Submission No** | K073351 – K071833 – K122771 |
| **Device Code** | ODP – Crystal<br>OVE – Mosaic and Vertu |

## IV. DEVICE DESCRIPTION

### Crystal

Crystal is an intervertebral body fusion device for use in cervical spinal surgery. The device is generally box-shaped with various holes throughout its geometry to allow for the placement of autograft. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned.

### Mosaic

The Mosaic Spinal Implant System is composed of a device body and fixation screws. The body is a generally box-shaped device with various holes located throughout its geometry for the placement of graft material. Additionally, it has teeth on its superior and inferior external surfaces to keep the device from migrating once placed in its desired location. The box-shaped body has projections (or flanges) that encompass screw holes. Screws pass through screw holes and affix to bone to help prevent implant migration.

### Vertu

The Vertu Cervical Intervertebral Body Fusion System is composed of an implant body and fixation screws. The implant body is a generally box-shaped device with holes through its body for the placement of graft material. Additionally, it has teeth located on its superior and inferior external surfaces to help keep the device from migrating once placed in its desired location. There are also screw holes located in the implant body. Screws pass through screw holes of the implant body and affix to bone to help prevent implant migration.

## V. INDICATION FOR USE

### Crystal®

The Crystal® device is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

The Crystal® device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine (i.e., anterior plate systems).

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

### Mosaic®

The Mosaic® device is an interbody fusion device intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two, three, or four screws. The maximum number of screws should be used to ensure adequate fixation of the impant.

**Vertu®**
The Vertu® device is a stand-alone interbody fusion device intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

Patients must have undergone a regimen of at least six (6) weeks non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the impant.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject Crystal, Mosaic and Vertu devices are identical in indications for use, surgical technique, design features and instrumentation to the predicate devices cleared in K073351, K071833 and K122771, respectively. The difference to the Crystal, Mosaic, and Vertu devices is the addition of the plasma sprayed commercial pure titanium coating on the superior and inferior surfaces of the devices. The performance of the Ti- coating is equivalent to the one of predicate Calix PC cleared in K112036. The addition of this coating does not raise any new issues of safety or effectiveness. In addition to the plasma sprayed commercial pure titanium coating on the Crystal device, line items (sizes) have been added to Crystal. Neither modification raises any new issues of safety or effectiveness.

## VII. PERFORMANCE DATA

**Biocompatibility Testing**
Biocompatibility testing were performed in accordance with FDA Memorandum #G95-1 and ISO 10993-1 Part 1. The Crystal, Mosaic and Vertu devices are considered permanent implant devices contacting tissue/bone.
The PEEK material biocompatibility relevant to the device contact type is presented in Invibio device master file (MAF 1209). The titanium coating material is commercially pure titanium. The coating is in accordance with ASTMF 1580, which address the biocompatibility of the material. No further testing were required,

**Electrical safety and electromagnetic compatibility (EMC)**

No electrical and electromagnetic compatibility testing were performed.

**Software Verification and Validation Testing**
The device does not contain software. Therefore no software verification and validation testing were performed.

**Mechanical testing**
Non-clinical testing were used to support the decision of substantial equivalence. Non-clinical testing consisted of the following testing performed in accordance with the FDA guidance Class II Special Controls Guidance Document: Intervertebral Body Fusion Device:

- Dynamic Torsion Testing ASTM F2077-03
- Gravimetric Measurement for Wear Assessment ASTM F2025-06
- Particle Characterization ASTM F1877-89
- Static Shear ASTM F1044-05
- Static Tension ASTM F1147-05
- Abrasion Resistance ASTM F1978-00

The wear debris data including number of particulates generated, and particulate size indicates that the device coating performs similarly to predicate Calix PC (K112036).

**Animal Study**
No animal studies were performed.

**Clinical Studies**
No clinical studies were performed.

## VIII. CONCLUSIONS

Based on our analysis of the test data, the device performs comparably to the predicate device that is currently marketed for the same intended use.